

70127-10

12/15/2010

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70127-10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 15 2010

Ms. Carrie Daniels (Agent for Novozymes Biologicals, Inc.)
Exponent
1150 Connecticut Ave., N.W.
Suite 1100
Washington D.C. 20036

Re: Novozymes Biologicals, Inc.
Metarhizium anisopliae Strain F52 Pesticide Products
EPA Registration Numbers 70127-7, 70127-8, 70127-9, 70127-10.
Confidential Statements of Formula (CSF) and Labels
Amendment Requests Dated June 23, 2010 and July 6, 2010

Dear Ms. Daniels:

The Agency has reviewed your above-referenced requests, on behalf of Novozymes. Biologicals, Inc., for amendments of Confidential Statements of Formula (CSFs) and labels under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c)(7). These requests that include manufacture of pesticides containing the active ingredient, *Metarhizium anisopliae* Strain F52, at both US (Salem VA) and Canadian Establishments (Saskatoon) with EPA Establishment numbers are granted as follows:

- The Confidential Statements of Formula (CSFs) for each of the products as specified below are acceptable for the non-food sites listed on the attached labels:
- CSF dated 06/23/10: TAE-001 Technical BioInsecticide (EPA Reg. No. 70127-7)
- CSF dated 06/23/10: Taenure Granular Bioinsecticide (EPA Reg. No. 70127-8)
- CSF dated 06/23/10: Tick-EX G (EPA Reg. No. 70127-9)
- CSF dated 11/02/10: Tick EX™ EC (EPA Reg. No. 70127-10)

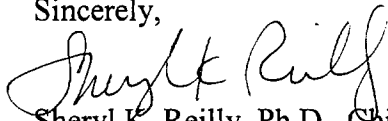
The enclosed stamped draft labels are approved for non-food use in urban and suburban residential areas until May 2, 2011, in accordance with the extensions granted August 08, 2010, with terms and conditions stated in the registration notices dated February 02, 2009.

You must submit final printed labels before releasing these products for shipment. If, at any time, EPA determines that additional data are required to maintain an existing conditional registration, the Agency will require such data under Section 3(c)(2)(B) of FIFRA. If you do not comply with these conditions, this registration is subject to cancellation under FIFRA section 6(e). Your release of this product for shipment constitutes acceptance of these conditions.

The Agency is reviewing the requests and submissions from Novozymes Biologicals, Inc. for food use and for amending the conditional registrations for the referenced pesticide products to an unconditional status under FIFRA Section 3(c)(5).

If you have any questions regarding these pesticides, please email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her at 703-308- 8097.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief

Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Enclosures: stamped draft labels

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[Front Panel]

TICK-EX™ EC

For Control of Ticks, Weevils, Thrips and Mites

ACTIVE INGREDIENT – <i>Metarhizium anisopliae</i> Strain F52*	% w/w 11.0%
OTHER INGREDIENTS**	89.0%
Total	100.0%

* Contains 4.9 x 10⁹ Colony Forming Units (CFU)/mL of Tick-Ex EC.

**Contains petroleum distillates

ACCEPTED

12/15/10

Under the Federal Insecticide, Fungicidal and Rodenticide Act, as amended, this pesticide registered under EPA Reg. No. 70127-10

KEEP OUT OF REACH OF CHILDREN
CAUTION
PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.	
NOTE TO PHYSICIAN	
Contains petroleum distillate. Vomiting may cause aspiration pneumonia.	

[Reviewer Notes: The "not for sale" date is to serve as the batch code.]

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Net Contents: 1 gallon
Not for Sale or Use after (insert date) _____

Produced For:
Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153
1-800-342-6173

EPA Establishment Number: [070127-VA-001]
[085238-CAN-001]
EPA Registration Number: 70127-10
Made in [USA] [Canada]

[Back Panel]

Personal Protective Equipment (PPE)

Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Mixer/loaders, applicators and other handlers of this product must wear a long-sleeved shirt and long pants, chemical resistant gloves such as nitrile rubber or butyl rubber, protective eyewear, and shoes and socks and a dust/mist filtering respirator with NIOSH prefix P-95 or R-95. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

- Users should remove clothing immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- Remove personal protection equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

This product contains an ingredient that is toxic to fish. This product is approved for residential (urban and suburban) outdoor terrestrial non-food uses. Do not use near endangered insect habitat. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300, day or night.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

GENERAL

TICK-EX EC is composed of spores of the arthropod pathogenic fungus *Metarhizium anisopliae* Strain F52. The spores of *Metarhizium anisopliae* attach to the surface of the arthropod, germinate and begin to grow. It will penetrate the exoskeleton of the arthropod and grow very rapidly inside the arthropod, causing the arthropod to die. It usually takes about one week, once the arthropod is exposed for death to occur.

APPLICATION INSTRUCTIONS

Apply TICK-EX EC to residential and institutional lawns and landscape perimeters. Apply at a rate of 2.0 to 3.0 fluid ounces of TICK-EX EC per 1000 ft². Use higher label rates when pest pressure is expected to be high. Apply using a minimum of 4 gallons of water per 1000 ft². Do not apply at pressures above 200 psi. Do not tank mix with fungicides.

PESTS CONTROLLED

- Ticks
- Weevils
- Thrips
- Mites

Applicators other than homeowners

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store TICK EX EC in its original container in a cool, dry locked place out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Homeowners

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store TAE-001 Technical Bioinsecticide in its original container in a cool, dry locked place out of reach of children and out of direct sunlight. Do not use or store near heat or open flame.

PESTICIDE DISPOSAL AND CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill container.

If empty:

Place container in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully.

Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. To the extent consistent with applicable law, buyers/users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above, customer's sole remedy for breach of warranty, to the extent consistent with applicable law, shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.